

House Study Bill 530 - Introduced

HOUSE FILE _____
BY (PROPOSED COMMITTEE
ON COMMERCE BILL BY
CHAIRPERSON PETERSEN)

A BILL FOR

1 An Act requiring health benefit coverage for certain cancer
2 treatment delivered pursuant to approved cancer clinical
3 trials and providing an applicability date.
4 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

1 Section 1. NEW SECTION. 514C.26 **Approved cancer clinical**
2 **trials coverage.**

3 1. *Definitions.* For purposes of this section, unless the
4 context otherwise requires:

5 a. "*Approved cancer clinical trial*" means a scientific
6 study of a new therapy for the treatment of cancer in human
7 beings that meets the requirements set forth in subsection 3
8 and consists of a scientific plan of treatment that includes
9 specified goals, a rationale and background for the plan,
10 criteria for patient selection, specific directions for
11 administering therapy and monitoring patients, a definition of
12 quantitative measures for determining treatment response, and
13 methods for documenting and treating adverse reactions.

14 b. "*Institutional review board*" means a board, committee, or
15 other group formally designated by an institution and approved
16 by the national institutes of health, office for protection
17 from research risks, to review, approve the initiation of,
18 and conduct periodic review of biomedical research involving
19 human subjects. "Institutional review board" means the same
20 as "institutional review committee" as used in section 520(g)
21 of the federal Food, Drug, and Cosmetic Act, as codified in 21
22 U.S.C. § 301 et seq.

23 c. "*Routine patient care costs*" means physician fees,
24 laboratory expenses, and expenses associated with the
25 hospitalization, administration of treatment, and evaluation of
26 a patient during the course of treatment which are consistent
27 with usual and customary patterns and standards of care
28 incurred whenever an enrollee, subscriber, or insured receives
29 medical care associated with an approved cancer clinical trial,
30 and which would be covered if such items and services were
31 provided other than in connection with an approved cancer
32 clinical trial.

33 d. "*Therapeutic intent*" means that a treatment is aimed
34 at improving a patient's health outcome relative to either
35 survival or quality of life.

1 2. *Coverage required.* Notwithstanding the uniformity of
2 treatment requirements of section 514C.6, a policy or contract
3 providing for third-party payment or prepayment of health or
4 medical expenses shall provide coverage benefits for routine
5 patient care costs incurred for cancer treatment in an approved
6 cancer clinical trial to the same extent that such policy or
7 contract provides coverage for treating any other sickness,
8 injury, disease, or condition covered under the policy or
9 contract, if the insured has been referred for such cancer
10 treatment by two physicians who specialize in oncology and
11 the cancer treatment is given pursuant to an approved cancer
12 clinical trial that meets the criteria set forth in subsection
13 3. Services that are furnished without charge to a participant
14 in the approved cancer clinical trial are not required to be
15 covered as routine patient care costs pursuant to this section.

16 3. *Criteria.* Routine patient care costs for cancer
17 treatment given pursuant to an approved cancer clinical
18 trial shall be covered pursuant to this section if all of the
19 following requirements are met:

20 a. The treatment is provided with therapeutic intent and is
21 provided pursuant to an approved cancer clinical trial that has
22 been authorized or approved by one of the following:

- 23 (1) The national institutes of health.
- 24 (2) The United States food and drug administration.
- 25 (3) The United States department of defense.
- 26 (4) The United States department of veterans affairs.

27 b. The proposed treatment has been reviewed and approved by
28 the applicable qualified institutional review board.

29 c. The available clinical or preclinical data indicate
30 that the treatment that will be provided pursuant to the
31 approved cancer clinical trial will be at least as effective
32 as the standard therapy and is anticipated to constitute an
33 improvement in therapeutic effectiveness for the treatment of
34 the disease in question.

35 4. *Applicability.*

1 cancer treatment in an approved cancer clinical trial to the
2 same extent that the policy or contract provides coverage for
3 treating any other sickness, injury, disease, or condition
4 covered under the policy or contract, if the insured has been
5 referred for such cancer treatment by two physicians who
6 specialize in oncology, and the cancer treatment is given
7 pursuant to an approved cancer clinical trial as set forth in
8 the bill.

9 The bill applies to specified classes of third-party payment
10 provider contracts or policies delivered, issued for delivery,
11 continued, or renewed in this state on or after July 1, 2010.